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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,318	03/26/2001	Susana Salceda	DEX-0199	1254

26259 7590 11/05/2003

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66 E. MAIN STREET  
MARLTON, NJ 08053

EXAMINER
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DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/05/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/817,318

Applicant(s)

SALCEDA ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 11 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): Sequence rule compliance.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 1a.Claim(s) objected to: none.Claim(s) rejected: 1b, 3-6.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1, 3-6 are examined in the instant application.

Claim 1a seems to be free of prior art and is allowable.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 1(b), 3-6 remain rejected under 35 USC 112, first paragraph, pertaining to lack of a clear written description for reasons already set forth in paper No: 13.

Applicant asserts that the claims have been amended to include a functional attribute as being upregulated in or specific to human mammary gland cancer tissue as well as the structural attributes of sharing 95% identity with the antisense sequence of SEQ ID NO:1. Applicant asserts that thus the claims as amended meet the written description requirement.

Applicant's arguments in paper No:14 have been considered but are found not to be persuasive for the following reasons:

Being upregulated in or specific to human mammary gland cancer tissue is not a specific function of the claimed polynucleotide. There is no disclosure of common structural attributes of the claimed variants, or any functional characteristics coupled with a known or disclosed correlation between structure and function. Thus the claims encompass unrelated sequences with unknown structure and function.

**REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE**

Claims 1(b), 3-4 remain rejected under 35 USC 112, first paragraph, pertaining to lack of enablement for a variant of SEQ ID NO:1 for reasons already set forth in paper No: 13. The amended claims 5-6 are rejected for the same reasons already of record.

Applicant asserts that the claims have been amended to include a functional attribute as being upregulated in or specific to human mammary gland cancer tissue as well as the structural attributes of sharing 95% identity with the antisense sequence of SEQ ID NO:1. Applicant asserts that it is routine to identify the claimed nucleic acid, using known methods for assessing % identity such as the methods taught by Sambrook et al. Applicant further asserts that methods for assessing unregulation and/or specificity of a polynucleotide sequence in human mammary gland cancer tissue are taught in the specification. Applicant concludes that therefore, it would not be undue experimentation to identify the claimed invention.

Applicant's arguments in paper No:14 have been considered but are found not to be persuasive for the following reasons:

Being upregulated in or specific to human mammary gland cancer tissue is not a function of the claimed polynucleotide. Further, being upregulated in or specific to human mammary gland cancer tissue is not a specific property of SEQ ID NO:1, which is shared with other unrelated sequences that are upregulated in or specific to human mammary gland cancer tissue. In addition, the specification and the claims do not recite which consensus sequence of SEQ ID NO:1 is necessary for the function of SEQ ID

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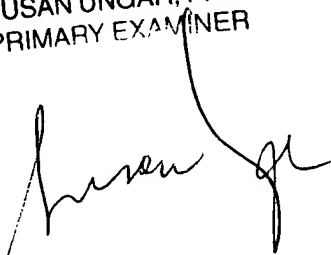
NO:1. The specification and the claims do not disclose how to make the claimed variants, which are capable of functioning as that which is being disclosed. Protein chemistry however is unpredictable, wherein even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein, as taught by Burgeess et al, Lazar et al, Tao et al, and Gillies et al, all of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan Ungar', is written over the printed name and title of the Primary Examiner.

MINH TAM DAVIS

October 20, 2003